

- II. Claims 2-4, drawn to a method for conjugating a label to a target involving hydrating a sequestered mixture of dry reagents.
- III. Claims 5 and 6, drawn to a method of conjugating a label to a target involving derivatizing a label with a heterofunctional reagent, activating the unreacted functionality of the heterofunctional reagent, followed by hydration step.
- IV. Claim 7, drawn to a vessel containing a derivatized label and an activating reagent in dry form.

III. ELECTION WITH TRAVERSE

Applicants provisionally elect, with traverse the claim of Group IV for further prosecution.

REMARKS

In the Office Action, it was stated that the inventions identified in the above-identified purported separate groups did not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lacked the same or corresponding special technical features for several reasons. First, it was asserted that the “vessels” of Groups I and IV contained no “special technical feature” in common since the vessels of each claims 1 and 7 contained different components. Second, the conjugation methods of Groups II and III involved combinations of different reaction steps using diverse reactants. Finally, it was asserted that neither of the methods of Groups II and III used the “vessels”, or the same components in the same form which were contained in the vessels of Groups I and IV. See Office Action, page 2. Applicants respectfully traverse the restriction requirement.

“A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involve at least one common or corresponding special technical feature.” MPEP 1893.03 (d), column 2, para 3. Such a unity of invention is demonstrated in the present claims because there is a shared technical feature of using dry form of at least one of the components in each of the Groups I through IV with the effect of controlling reaction among the components. Claim 1 (Group I) is directed to a single vessel containing NHS, a label and a carbodiimide that are all held in dry form suitable for rehydration at pH of about 7. Claim 2 (Group II) recites a method for conjugating the label to a target moiety comprising the step of storing the three components in dry form and hydrating the

components to initiate reaction between them. Claim 5 (Group III) recites a method of conjugating a label to target moiety comprising derivitizing a label and placing the dry form of the derivatized label in a container with an activating agent whereby the derivatized label and activating reagent are sequestered from reaction with each other until hydration. Claim 7 (Group IV) recites a single vessel containing a derivatized label and an activating agent being held in dry form suitable for rehydration.

In each of the Groups I-IV, the components are held in dry form suitable for rehydration, and reaction of the components is precluded prior to the rehydration. Therefore, the restriction requirement is improper because the use of dry form to control the labeling reaction constitutes common special technical feature among Groups I through IV under PCT Rule 13.1.

Additionally, Applicants believe that claims of Groups I and II, and that of Groups III and IV could be independently considered to have unity of invention under 37 C.F.R. 1.475 (b). Claims of Groups I and II are related as a product and a process specially adapted for the manufacture or use of the said product. Likewise, claims in Group III and IV are related as a process and an apparatus or means specifically designed for carrying out the said process wherein the single vessel or container containing the components is specifically designed to carry out the method of conjugating the label to a target moiety in Group III. This is emphasized by 37 C.F.R. 1.475(b) which indicates, in pertinent part, that:

...a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) ...
- (2) ...
- (3) A product, a process specially adapted for the manufacture of the said product, and use of the said product, or
- (4) A process and an apparatus or means specifically designed for carrying out said process; ...

Please also see, *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 590 USPQ 231 (E.D. Va. 1986) wherein the court held that a U.S. national stage of a PCT application

containing claims directed to a process and apparatus for its practice must be examined in the same application since they satisfy the requirement of unity of invention of the PCT rules. The same principle applies to claims directed to a method for conjugating a label to a target and the vessel containing the components in dry form in claims of Group III and IV of this application.

In view of the above remarks, it is respectfully requested that the restriction requirement be withdrawn and that all claims be examined in the same application. Alternatively, however, in the event that the first argument regarding the unity of invention under the PCT rules is not deemed to be met by the common technical feature of using the dry form in all of the purported Groups, Applicants respectfully request that the Examiner combine claims of Groups I and II and that of Groups III and IV for further prosecution in light of 37 C.F.R. 1.475(b).

However, in the event that the restriction requirement is made final, and in order to comply with 37 C.F.R. 1.143, Applicants provisionally elect claim 7 (Group IV), holding the remaining claims (Groups I, II and III) in abeyance under the provision of 37 C.F.R. 1.142(b) until final disposition of the elected claims.

IV. REQUEST FOR ALLOWANCE

Applicants submit that all claims are in condition for allowance, an indication of which is solicited. If any outstanding issues remain, Applicants would appreciate a telephone call to the undersigned counsel to resolve such issues in a expeditious and effective manner.

Respectfully submitted,  
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